REMARKS

In response to the Office Action mailed September 6, 2006, Applicants respectfully request that the Examiner reconsider the above-captioned application in view of the foregoing amendments, the following comments.

Objection to the Specification

The Examiner has objected to the specification for failing to provide proper antecedent basis for the claimed subject matter. In particular, the Examiner asserts that the limitation "rigidly attached" and "rigidly" found in Claims 1, 32 and/or 33 are not found in the written disclosure and correction of the specification is required.

Further to a telephonic interview with the Examiner, Applicants have amended Claims 1, 32 and 33 to remove the term "rigidly" and insert the term "directly" to describe various connection points between the connecting member and other components. Support for this amendment is shown in the Figures, particularly Figure 2A through 2G, which show the connecting member 105 directly attached to the anchor structure 104 and/or proximal collar 108. Additional support can be found in the specification, page 20, line 8 to page 21, line 12, which describes the components being attached by welding or mechanically attaching them together, or by fabricating the structural frame by cutting the structure from sheet or tube stock as is known in the art. In each case the component parts, particularly the connecting members 105 and anchor structure 104 are directly attached to one another.

In addition to the foregoing, Claims 1, 32 and 33 state that the second end of the cantilever valve strut is free to deflect in at least a radial direction from the longitudinal axis. The Examiner has requested clarification as to what is meant by this limitation.

Further to the telephonic interview with the Examiner, the deflection of the free end of the cantilever valve strut in at least a radial direction is best illustrated in Figures 4A, 4B, 5A, and 5B. Figures 4A and 4B are perspective and section views, respectively, illustrating one embodiment of the prosthetic valve in the open position. As can be seen, the cantilever valve

struts 107 in this position are closely arranged around the longitudinal centerline of the structural frame. See Figure 4B. Conversely, Figures 5A and 5B show perspective and section views, respectively, illustrating one embodiment of prosthetic valve in the closed position. As can be seen, the cantilever valve struts 107 in this position are circumferentially arranged around the longitudinal centerline of the structural frame, at some distance from the longitudinal axis. One can appreciate that the free end of the cantilever valve strut 107 must move outward from the longitudinal axis in a radial direction (in the direction of a radius from the longitudinal centerline) when the valve goes from the open position (Figure 4A and 4B) to the closed position (Figure 5A and 5B). The first end of the membrane assembly is attached along the second end of the cantilever valve strut and similarly moves in a radially outward direction from the longitudinal axis.

The Applicants have amended the specification as noted above to clarify this structure and respectfully request that the Examiner withdraw his objection of the specification.

Rejection of Claims 1-5, 8, 9, 22, 24, 27-29, 32 and 33 under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1-5, 8, 9, 22, 24, 27-29, 32 and 33 under 35 U.S.C. § 102(e) as being anticipated by Huter et al. (6,511,496). The Examiner alleges that Figure 1 shows a prosthetic valve having an anchor structure (tubular stent) on a balloon, which is attached to a catheter device that has a collar 40 proximal to the anchor. The Examiner further alleges that the collar 40 is attached to a cantilever strut assembly 24 having a membrane assembly 22 attached thereto, and that a connecting member 26 is indirectly attached to the collar 40.

The Applicants respectfully assert that the structure cited in Huter et al. does not disclose all the elements claimed in Applicants' independent Claims 1, 32 or 33. Applicants have amended these Claims to more clearly illustrate this distinction.

Huter et al. Does Not Disclose a Connecting Member Directly Attached to the Anchor

The Examiner alleges that the guide wire (element 26) in Huter can be construed as the connecting member, and the stent (unidentified in Huter figures) can be construed as the anchor structure, in Applicant's claimed invention. Assuming, *arguendo*, that the guidewire 26 is considered a connecting member, the stent is not directly connected to the guidewire as required by Applicant's Claims 1, 32 and 33. Instead, Huter states that once the balloon angioplasty procedure is complete, the balloon catheter 28 is removed and may be followed by a stent-delivery catheter (not shown) for placement of a stent across the dilated lesion. See col. 5, lines 57-61. See Col. 5, lines 45-63. Accordingly, the stent (and stent delivery catheter) slide over the guidewire, and thus cannot be directly attached to the guidewire.

Similarly, the balloon and/or balloon/stent alleged by the Examiner to be present in Huter is not an anchor structure and is not directly attached to the connecting member. Instead the balloon in Huter is used to perform an angioplasty procedure and radially expand or dilate artherosclerotic plaque. See col. 5, lines 45-57. The balloon 30 is attached to a balloon dilatation catheter 28 that is advanced over the guidewire 26. See col. 5, lines 45-55. The filter device containing the strut assembly 24 is rotatably mounted on the distal end of the guidewire 26. See col. 5, lines 37-38. Because the balloon catheter 28 is back loaded and advanced over the guidewire 26, the balloon 30 cannot be directly attached to any component of the filter device or guidewire.

Claims 1, 32 and 33 clearly require the anchor assembly to be directly attached to a first end of the connecting member, and a cantilever strut to be cooperatively associated or attached to the second end of the connecting member.

Accordingly, Huter et al. does not disclose a connecting member directly attached to the anchor and cannot anticipate Claims 1, 32 and 33 in the present application.

Huter Does Not Disclose a Collar Proximal to the Anchor

Claim 33 claims a collar located proximal to the radially expandable anchor. The term "proximal" as defined in the specification describes an upstream member, section or relative position. See page 14, line 20-23. That is to say, the collar in Claim 33 is located upstream from the radially expandable anchor.

Conversely, The collar 40 in Huter is located downstream or distal to the expandable anchor. Accordingly, Huter et al. cannot anticipate Claim 33 of the present application.

Huter Does Not Have an Anchor Structure

Claims 1, 32 and 33 of the present application describe and claim an expandable structure, including an anchor structure having first and second open ends, and at least one connecting member directly attached to the anchor structure. Claims 32 and 33 require the anchor structure to be formed from a lattice of interconnected elements. The first end of the connecting member is directly attached to the second end of the anchor structure. Claims 1 and 32 further claim that the second end of the connecting member is cooperatively associated with one end of a cantilever valve strut. Claim 33 claims a connecting member where the second end of the connecting member is directly attached to the proximal collar. The Examiner alleges that Huter discloses an anchor structure (tubular stent) on a balloon, which is attached to a catheter device. However, the Examiner has not clearly pointed out what member in Figure 1 represents the anchor structure, and there is nothing in Huter disclosing an anchor structure on the balloon. Figure 1 depicts an angioplasty balloon back loaded over a guidewire. There is some kind of geometric shape on the balloon (represented but not identified in the figure), but is not described in the specification. The examiner seems to argue that this is an anchor structure (tubular stent) having first and second open ends as recited in Applicants' Claim 1, 32 and 33. However, the Applicants respectfully assert that this could just as easily be ribbing or a textured surface on the balloon outer surface, as is known in the art, to prevent slipping across the lesion. The specification does mention a stent, which could arguably be construed as an anchor structure, but

the specification states that once the balloon angioplasty procedure is complete, the balloon catheter 28 is removed and may be followed by a stent-delivery catheter (not shown) for placement of a stent across the dilated lesion. See col. 5, lines 57-61. This implies that dilation balloon does not have a stent over its outer surface. In addition, the specification specifically states that the stent-delivery catheter is not shown, intimating that the stent is not shown in the figures.

Huter Does Not Disclose Cantilever Valve Struts

Claims 1, 32 and 33 of the present application claim a cantilever valve strut having first and second ends, where the first end of the cantilever valve strut is cooperatively associated with the second end of the connecting member, and the second end of the cantilever valve strut is free to deflect at least radially from the longitudinal axis. The Examiner alleges that the cantilever valve strut assembly is expandable strut assembly 24.

The Applicants assert that the strut assembly 24 is not a cantilever valve strut. Instead, the strut assembly 24 in Huter is made up of individual struts 44. It is these struts 44 that are more appropriately akin to the valve struts claimed in the present application. However, it is clear from Figure 3 that the struts 44 in Huter are not cantilever valve struts as claimed by Applicants. Instead the struts 44 in Huter are fixed at both ends to collars 40 and 42. Even assuming that strut assembly 24 may be construed as a structurally equivalent member to the cantilever valve strut in Claims 1, 32 and 33, the strut assembly 24 is also not a cantilevered member. That is to say, the strut assembly 24 does not have an end that is capable of being free to deflect at least radially from the longitudinal axis.

It is well known that a cantilever member is fixed on one end, having a second end that is free to deflect and move. The first end of the strut assembly 24 in Huter is attached to collar 40, but the second end is not free to deflect. Indeed the guidewire is slid through the second end of the strut assembly 24, restraining the second end and only allowing longitudinal movement of the strut assembly 24 relative to the guidewire. This arrangement is more akin to a beam fixed

on one end by a pin, while the second end is allowed to slide on a roller, which is not considered a cantilevered member.

Because Huter et al fails to disclose each of the elements recited by independent Claims 1, 32 and 33, Huter cannot anticipate Applicants' claimed device under 35 U.S.C. §102(e). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claim 1, 32 and 33 under 35 U.S.C. § 102(e) as being anticipated by Huter. As Claims 2-22, 24, and 27-29 depend directly or indirectly from independent Claim 1, Applicants similarly request that the Examiner withdraw the rejection to these claims under 35 U.S.C. § 102(b) as being anticipated by Huter. Further, Applicants assert that Claim 1 is an allowable generic claim linking Claims 23, 25, 26, 30 and 31. Accordingly, Applicants respectfully request the Examiner reinstate and allow these claims.

Rejection of Claim 11 under 35 U.S.C. § 103(a)

The Examiner rejected Claim11 under 35 U.S.C. § 103(a) as being unpatentable over Huter et al, in view of Konya et al. (6,368,338). The Examiner admits that Huter fails to disclose that the membrane material comprises a reinforcement fiber, but that Konya teaches that the filtering device can include reinforcement of structural fibers.

For the reasons stated above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. Claim 11 depends indirectly from Independent Claim 1. As a result, Huter in view of Konya fails to teach all the claim limitations of dependent Claims 11. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 11 under 35 U.S.C. § 103(a).

Konya does not Teach a Membrane Having Reinforcement Structural Fibers

Konya does not disclose a valve device, a filter device or a fiber reinforced membrane. Instead, Konya discloses an occlusion device for occluding a vessel. The occlusion device

comprises elastically deformable members 12 and a jacket 16. In the specification section cited by the examiner (col. 12, lines 23-31), polyester threads are used as an occluding agent 20 to facilitate quicker occlusion by providing more sites for thrombosis to occur. See also Figure 11. The polyester threads are not reinforcement fibers, and particularly not reinforcement fibers contained in a synthetic membrane used as a valve.

Conversely, the present invention clearly describes and claims a valve membrane having reinforcement fibers to further support the membrane.

Accordingly, Huter and Konya individually or in combination do not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Konya fails to teach all the claim limitations of dependent Claim 11. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 11 under 35 U.S.C. § 103(a).

There is no Teaching or Suggestion to Combine the References

A rejection under 35 U.S.C. § 103(a) requires that the Examiner make a factual showing that the claimed subject matter, as a whole, would have been obvious to a person of ordinary skill in the art. The combination of two or more references is only proper if there is some objective teaching in the prior art that would lead one of ordinary skill to combine the relevant references. The references must be taken in their entireties. It is impermissible within the framework of 35 U.S.C. § 103 to pick and choose from a reference only so much of it as will support a conclusion of obviousness. Accordingly, it is the Examiner's affirmative duty to show such a teaching in the art.

The Applicants respectfully assert that the Examiner has not met his burden under 35 U.S.C. § 103(a). The Examiner merely states that Konya teaches that the filtering device can include reinforcement or structural fibers, and that it would have been obvious to use reinforcement fibers as taught by Konya with the membrane of Huter such that is strengthens the apparatus and prevents collapse. The Examiner has not made an affirmative showing that the two references should be combined.

Huter discloses an embolic protection device or filter for capturing embolic particles entrained in blood flowing in an arterial vessel during interventional procedures. The filter includes an expandable strut assembly and a filtering medium. The filtering medium is formed from a thin elastic polymer membrane containing a plurality of holes that allow blood to pass through the filter while capturing embolic particles. See Abstract generally. Konya teaches an occlusion method and apparatus for creating a thrombus in a vessel for occlusion of the vessel. The devices each serve completely different functions, are different devices, and do not teach or suggest any combination of the two devices.

Applicants assert that Huter is not properly combinable with Konya for a rejection under 35 U.S.C. § 103(a). Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 11 under 35 U.S.C. § 103(a).

Rejection of Claims 6 and 7 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Quijano et al. (5,500,014). The Examiner asserts that Huter meets the claim limitations of Claim 1, but does not disclose that the use of biological vein material for the membrane.

As discussed above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Quijano fails to teach all the claim limitations of dependent Claims 6 and 7. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 6 and 7 under 35 U.S.C. § 103(a).

Rejection of Claims 10, and 12-21 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 10 and 12-21 under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Alt et al. (5,788,979). The Examiner asserts that Huter meets the claim limitations of Claim 1, but does not disclose that the structural frame or membrane is

covered with a therapeutic agent. However, the Examiner asserts that Alt teaches that biodegradable polymer materials can be loaded with drugs or pharmaceutical agents.

As discussed above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Alt fails to teach all the claim limitations of dependent Claims 10 and 12-21. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 10 and 12-21 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully assert that the present application is now fully in condition for allowance, and such action is respectfully requested. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number listed below.

No additional fee is thought to be necessary to enter this Amendment and Response. If an additional fee is required, the Examiner is authorized to charge the Applicants' Deposit Account - Account Number 10-0750/CRD-5051USNP.

Respectfully submitted,

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